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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/525,345

08/17/2005

Garth James Smith Cooper

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3912

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EXAMINER

PACKARD, BENJAMIN J

ART UNIT

PAPER NUMBER

1612

MAIL DATE

DELIVERY MODE

02/18/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/525,345	Applicant(s) COOPER ET AL.	
	Examiner Benjamin Packard	Art Unit 1612	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 November 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 129-171 is/are pending in the application.
- 4a) Of the above claim(s) 162-171 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 129-161 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Applicants' arguments, filed 11/28/08, have been fully considered. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Response to Election/Restrictions

Applicants request further consideration with regards to the election/restriction without providing any reasoning into why reconsideration is requested.

Without any guidance, Examiner again notes this is a national phase of a 371 filing, and therefore the unity of invention standard applies. Where such unity was broken, as evidenced by the art cited in the restriction, the inventions may properly be restricted.

Claim Rejections - 35 USC § 112 -- New Matter

Claims 146-161 were rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement, lacking support the limitation wherein triethylenetetramine and succinic acid are purified.

Applicants assert at page 30 that the reference teaches the removal of solvent inherently produces a purified acid addition salt.

Examiner notes first that a purification step within a specific reaction does not provide support for the broad "purified" compound. Further, while Applicants assert the

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step "inherently" provides a purified acid addition salt, it is noted that there may still be unreacted starting products where only the inert solvent is removed by evaporation.

Therefore, it does not appear that the product is even inherently purified.

Claim Rejections - 35 USC § 112 -- Written Description

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 160 and 161 are rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention where the phrases "delivery agent" and "reverse active transport agent" are used.

Applicants assert pages 73-77 of the Application disclose ample description and examples, further that such are known to one skilled in the art.

Examiner notes that pages 73-77 appear to disclose bioavailability and absorption enhancing agents, but the term "delivery agents" is much broader than the limited disclosed groups and the broader genus does not have written description supported based on the description of a limited sub-genus.

Additionally, there does not appear to be any disclosure of reverse active transport agents, such to provide support with regards to written description.

Claim Rejections - 35 USC § 103

Claims 129-161 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wang et al. (US 2003/0055113).

It is unclear what Applicants argument is, but Applicant appears to assert Wang contemplates a different form of administration, which uses ophthalmologically acceptable carriers, and therefore does not provide motivation to use the organic salt.

Wang et al specifically teaches administration to a patient " one or more of the above-identified copper chelators or a pharmaceutically acceptable derivative or salt thereof in a pharmaceutically acceptable carrier or diluent" (paragraph 45). Such teaching provides explicit motivation to adapt the compounds disclosed into the various salt forms. As previously cited, succinic acid is also specifically disclosed as a potential salt (paragraph 46). One of ordinary skill in the art would then select from among the optional salts to result in the instantly claimed compound.

Note, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art composition is capable of performing the intended use, then it meets the claim. Here, the intended administration forms of claims 147-159 are met where both compositions contain the same active ingredient and are suitable to be included in such administration forms. Even if the intended administration forms are given patentable weight, Wang et al explicitly teaches administering the active agent via the various

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forms of administration, "for example, orally, parenterally, intravenously, intradermally, or subcutaneously." (paragraph 45)

Conclusion

No claims allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Benjamin Packard whose telephone number is 571-270-3440. The examiner can normally be reached on M-R 8-5 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Frederick Krass can be reached on 571-272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Benjamin Packard/
Examiner, Art Unit 1612

/Frederick Krass/

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Supervisory Patent Examiner, Art Unit 1612